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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,406	08/02/2001	Zohar Yakhini	10010313-1 (2003309-0012)	6019

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AGILENT TECHNOLOGIES
Legal Department, 51UPD
Intellectual Property Administration
P. O. Box 58043
Santa Clara, CA 95052-8043

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/20/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant No.

09/921,406

Applicant(s)

YAKHINI ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-4 (in part), as solely drawn to a method of diagnosing an aggressive form of cancer comprising providing a genetic sample from a test sample of a tumor and analyzing expression of Wnt5a, classified in class 435, subclass 6.
- 2-20. Claims 1-3(in part), as solely drawn to a method of diagnosing an aggressive form of cancer comprising providing a genetic sample from a test sample of a tumor and analyzing expression of ONE gene from those listed in Claim 1, classified in class 435, subclass 6.

(Upon election of any one of Groups 2-20, applicant should identify the particular gene of interest as listed in Claim 1 as each gene is an independent and distinct invention, not a species).

21. Claims 5-6, 9 drawn to a method of treating a patient diagnosed with malignant melanoma comprising administering an agent known to inhibit Wnt5a wherein said agent reduces the expression of Wnt5a, classified in class 514, subclass 1.
22. Claims 5,7,9 drawn to a method of treating a patient diagnosed with malignant melanoma comprising administering an agent known to inhibit Wnt5a wherein said agent is an antisense molecule, classified in class 800, subclass 286.

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23. Claims 5,8-9 drawn to a method of treating a patient diagnosed with malignant melanoma comprising administering an agent known to inhibit Wnt5a wherein said agent reduces the activity of Wnt5a , classified in class 424, subclass 184.1.

24. Claims 10-13 (in part), as solely drawn to a kit comprising at least a portion of at least one gene wherein said gene is Wnt5a, classified in class 435, subclass 810.

25-43. Claims 10-11,13 (in part), as solely drawn to a kit comprising at least a portion of at least one gene ONE gene as listed in Claim 10, classified in class 435, subclass 810.

(Upon election of any one of Groups 25-43, applicant should identify the particular gene of interest as listed in Claim 10 as each gene is an independent and distinct invention, not a species).

44. Claims 14-15 (in part), as solely drawn to a kit comprising an antibody directed against one protein wherein said protein is Wnt5a, classified in class 435, subclass 810.

45-63. Claim 14 (in part), as solely drawn to a kit comprising ONE antibody directed against ONE protein from those listed in Claim 14, classified in class 435, subclass 810.

(Upon election of any one of Groups 45-63, applicant should identify the particular protein of interest as listed in Claim 14 as each protein is an independent and distinct invention, not a species).

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64. Claims 16-20, drawn to a method of screening for agents useful in the treatment of cancer comprising providing a cell expressing Wnt5a, providing an agent to be screened, contacting the cell with the agent, detecting a change in expression or activity of Wnt5a in the cell, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups 24-63 represent separate and distinct kits comprising distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The Inventions of Groups 1-23, and 64 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. With regards to Groups 21-23, although drawn to treating a patient diagnosed with melanoma, each Group comprises distinct method steps that requires distinct reagents and dosages. For example, an agent that reduces the activity of Wnt5a is interpreted as those agents which inhibit the functional activity of the polypeptide, while an agent that reduces the expression of Wnt5a is interpreted as any agent that interrupts the transcriptional machinery of the Wnt5a gene.

The invention of Group 24 and the method of Group 1 are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different

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product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the kit products as claimed can be used in a materially different process such as screening for agents useful in the treatment of cancer.

The invention of Groups 25-43 and the method of Groups 2-20 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the kit products as claimed can be used in a materially different process such as screening for agents useful in the treatment of cancer or affinity chromatography.

The invention of Groups 44-63 and the methods of Groups 1-23, 64 are not at all related because the kits of Group 44-63 are not used in any of the methods of Groups 1-23, and 64.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Election

Group 64 (Claim 19) is generic to a plurality of disclosed patentably distinct species comprising the following:

- a) polynucleotides
- b) proteins or peptides
- c) small molecules

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
May 16, 2003

A handwritten signature in cursive script, appearing to read "Gary B. Nickol", written in black ink.